IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC, Plaintiffs, v. BARR LABORATORIES, INC. Defendants.	)	C.A. No. 06-286-GMS

PLAINTIFFS' OPENING BRIEF ON CLAIM CONSTRUCTION

ASHBY & GEDDES
Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19801
302-654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
tlydon@ashby-geddes.com

Attorneys for Plaintiffs
Aventis Pharmaceuticals Inc. and
Sanofi-Aventis US LLC

Of Counsel:

Paul H. Berghoff
Joshua R. Rich
Jeremy E. Noe
McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

Dated: September 10, 2007
183975.v1

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

I. PROCEDURAL HISTORY

On May 2, 2006, Plaintiffs Aventis Pharmaceuticals Inc. and Sanofi-Aventis US LLC (collectively, "Aventis") filed this action against Defendant Barr Laboratories, Inc. ("Barr") pursuant to 35 U.S.C. § 271(e)(2) for infringement of U.S. Patent Nos. 5,976,573 ("the '573 patent") and 6,143,329 ("the '329 patent") (collectively, "the patents-in-suit"). (D.I. 1.) Barr's act of infringement was the filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Aventis's Nasacort® AQ Triamcinolone Acetonide aqueous nasal spray.

The Court entered a Scheduling Order on July 18, 2006, pursuant to which the parties' claim construction briefs were due on September 7, 2007 (later extended to September 10, 2007). (D.I. 23.) On August 24, 2007, the parties submitted a Joint Claim Construction Chart that narrowed contested claim terms to those addressed herein. (D.I. 114.) This Court's *Markman* hearing to construe these contested claim terms is scheduled for October 31, 2007. (D.I. 23.)

II. SUMMARY OF ARGUMENT

Aventis contends that the disputed terms of the asserted claims of the '573 patent (claims 1-10, 21-24, 26-30, and 34-35) and of the '329 patent (claims 1, 3, 4-17, and 22-26) have the following meanings:

Disputed Claim Term	**Aventis's Construction**
Aqueous pharmaceutical composition	A water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation
Mucosal surfaces	Bodily tissues which line the nasal cavity
Pharmaceutically effective amount	An amount that exerts the pharmacological action of the medicament

Thixotropic	"Thixotropic" refers to the characteristics of a composition which exhibit a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed
the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein	The viscosity of the composition at rest during non-use is sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition "Relatively high" viscosities range from about 400 to about 1000 cps when measured by the method disclosed in the specification
as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity	Upon application of shear force, the viscosity of the composition decreases sufficiently to allow the composition to flow freely through a pump orifice and break up into a fine mist that can infiltrate and deposit on mucosal regions "Relatively low" viscosities range from about 50 to about 200 cps when measured by the method disclosed in the specification
in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity	Upon removal of shear force and in relatively unstressed form following deposition on mucosal surfaces, the viscosity of the composition increases to a relatively high value such that the composition is retained on the mucosal surfaces on which it is deposited and resists being swept away by mucocillary clearance forces, and reverts to the viscosity in unsheared form "Mucocillary forces" are those that cause mucocillary clearance

Aventis's proposed constructions for these disputed terms are based on the ordinary meanings of the terms and are supported by and entirely consistent with both the claim language as a whole and the other intrinsic evidence. By contrast, Barr's proposed construction of those terms ignores the ordinary and common sense meanings of the terms, offers multiple and inconsistent

meanings for the same terms used in different claims, violates canons of claim construction, and attempts to import limitations from the preferred embodiments. The ordinary meaning of the words of the claims, in their context, coupled with the patent specification and prosecution history, indicate that this Court should adopt Aventis's proposed claim constructions.

III. FACTUAL BACKGROUND

A. TAA Aqueous Nasal Sprays

The patents-in-suit relate to triamcinolone acetonide ("TAA") aqueous nasal sprays. TAA is an anti-inflammatory steroidal drug. A5 ('573 patent, col. 4, l. 1-5). In the form of Nasacort® AQ, it is approved by the FDA to treat seasonal and perennial allergic rhinitis, both of which involve (among other symptoms) inflammation of the mucous membranes of the nose. A363 (Nasacort AQ Product Insert); *see also* A4 ('573 patent, col. 1, l. 12-14).

An estimated forty million Americans suffer from seasonal or perennial allergic rhinitis, and it is thought that many millions more suffer from these conditions worldwide. A4 ('573 patent, col. 1, l. 17-19). Symptoms of allergic rhinitis include nasal itch, congestion, runny nose, sneezing, and watery eyes. A4 ('573 patent, col. 19-21). Seasonal allergic rhinitis ("SAR") is commonly referred to as "hay fever." A4 ('573 patent, col. 1, l. 21-22). It is caused by allergens which are present in the air at specific times of the year, such as tree pollen in spring. A4 ('573 patent, col. 1, l. 22-25). Perennial allergic rhinitis ("PAR") is caused by allergens which are present in the environment year round, such as dust mites, mold, mildew, and pet dander. A4 ('573 patent, col. 1, l. 25-28).

For maximum effectiveness, an aqueous TAA nasal spray must have a combination of desired properties. A4 ('573 patent, col. 1, l. 38-40). For example, the spray must be easily deliverable to targeted tissues in the nasal cavity. A5 ('573 patent, col. 1, l. 40-44). The spray's

TAA component should remain in contact with the target tissues for an extended time, which requires being capable of resisting clearance by physiological forces that continuously function to remove particles from the nose (referred to as "mucocillary clearance."). A5 ('573 patent, col. 1, l. 38-56). Furthermore, the composition should minimize patient discomfort, be stable and have suitable shelf life, and not be composed of ingredients that are detrimental to the patient or environment. A5 ('573 patent, col. 1, l. 58-63). At the time the applications underlying the patents-in-suit were filed, this combination of formulation characteristics was unavailable except in the patented formulation.

B. The '573 Patent

The '573 patent, entitled "Aqueous-based Pharmaceutical Composition," issued on November 2, 1999 from Application Serial No. 08/678,465 ("the '465 application"). A1. Aventis is asserting independent claims 1, 5, 21, and 34 of the '573 patent against Barr, as well as dependent claims; all of the claim construction disputes arise out of the language of the independent claims. The asserted independent claims of the '573 patent recite as follows (with disputed terms bolded):

> 1. An **aqueous pharmaceutical composition** which is capable of being sprayed into the nasal cavity of an individual and which comprises:
>
> (A) a **pharmaceutically effective** amount of solid particles of triamcinolone acetonide which is effective in treating an abnormal bodily condition by virtue of its being present on the **mucosal surfaces** of the nasal cavity; and
>
> (B) a suspending agent in an amount effective to maintain said particles dispersed uniformly in the composition and to impart to the composition the following **thixotropic** properties:
>
> (i) **the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein**;
>
> (ii) **as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such**

that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity; and

(iii) **in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity**.

5. An **aqueous pharmaceutical composition** which is capable of being sprayed into the nasal cavity of an individual, which is odorless, propellant-free, and has a pH of about 4.5 to about 7.5, and which comprises:

(A) at least about 85 wt. % of water;

(B) about 0.001 to about 2 wt. % of solid particles of triamcinolone acetonide medicament;

(C) about 1 to about 5 wt. % of a suspending agent comprising a mixture of about 85 to 95 wt. % of microcrystalline cellulose and about 5 to about 15 wt. % of carboxymethyl cellulose based on the weight of the mixture, the amount of suspending agent being effective to maintain said solid particles dispersed uniformly in the composition and to impart to the composition the following **thixotropic** properties:

(i) **the viscosity of the composition in unsheared form is about 400 to about 800 cp**;

(ii) **as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition is about 50 to about 200 cp and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity**; and

(iii) **in deposited form on the mucosal surfaces, the viscosity of the composition is about 400 to about 800 cp and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity**; and

(D) about 0.004 to about 0.02 wt. % of a quaternary ammonium compound that has anti-microbial properties; and

(E) about 0.01 to about 0.5 wt. % of a chelating agent.

21. A method for treating allergic rhinitis in an individual comprising applying to the **mucosal surfaces** of the nasal cavities of an individual a composition according to claim 5 by spraying a dose of the composition into each of the nasal cavities of the individual, said dose containing a **pharmaceutically effective amount** of said medicament and depositing **pharmaceutically effective amounts** of the medicament on each of the

> **mucosal surfaces** of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the **mucosal surfaces** which overlie the turbinates covering the conchas and such that **pharmaceutically effective amounts** of the medicament are retained on each of said **mucosal surfaces** for at least about an hour.
>
> 34. A method for applying solid particles of triamcinolone acetonide to the **mucosal surfaces** of the nasal cavities comprising spraying a dose of an **aqueous pharmaceutical composition** containing said medicament into each of the nasal cavities, said dose containing a **pharmaceutically effective amount** of triamcinolone acetonide, said composition including also a suspending agent in an amount which is effective in maintaining said particles dispersed uniformly in the composition and in imparting to the composition **thixotropic** properties such that **pharmaceutically effective amounts** of triamcinolone acetonide are deposited on each of the **mucosal surfaces** of the anterior regions of the nose, the frontal sinus and the maxillary sinuses, and on each of the **mucosal surfaces** which overlie the turbinates covering the conchas and such that portions of said amounts are retained on each of said **mucosal surfaces** for at least about an hour.

The '573 patent specification provides assistance in determining the definition of the claim terms in dispute. For example, the Field of the Invention explains that:

> The field of the present invention is described initially in connection with the treatment of particular forms of rhinitis, that is, an abnormal bodily condition that involves inflammation of the mucous membrane of the nose. It should be understood that the invention has broader applicability, as will be described below.

A4 ('573 patent col. 1, l. 11-16). That passage provides support for the proposition that the claims at issue are not limited to the treatment of allergic rhinitis. Similarly, it is clear from the following quote that mucosal surfaces are bodily tissues that line the nasal cavity:

> Such an agent is generally used by spraying it into the nasal passages of the human patient where it deposits on surfaces of the mucosa which line the nasal cavities.

Id, (*Id* at col. 1, l. 32-35). Furthermore, the Field of the Invention section provides a context for the construction of an aqueous pharmaceutical composition, because the composition must be non-toxic to satisfy the requirement:

> The present invention relates to a pharmaceutical composition which has a combination of properties that make it particularly effective and suitable for relieving abnormal bodily conditions that can be treated by depositing the composition on the surface of the mucosa which line the nasal passages.

Id, (*Id* at col. 1, l. 64 - col. 2, line 2). The Detailed Description of the Invention section of the specification also provides context for the construction of the claims. For example, the construction of the term "aqueous pharmaceutical composition" is informed by:

> The water-based composition of the present invention comprises a medicament in the form of solid particles and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation.

Id, (*Id* at col. 3, l. 45-50), and:

> Water is present in the composition in a major amount.

Id, (*Id* at col. 3, l. 55). Moreover, this section provides context for use of the term thixotropic in the claims:

> The viscosity of the composition at rest is relatively high, for example, about 400 to about 1000 cp. As the composition is subjected to shear forces, for example, upon being subjected to forces involved in its being agitated before spraying, the viscosity of the composition decreases (for example, to about 50 to about 200 cp) and it flows readily through the spray device and exits therefrom in the form of a fine plume which infiltrates and deposits on the mucosal surfaces of at least the following parts of the nose: the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses; and the turbinates which overlie the conchas of the nasal cavities. Thus, the thixotropic composition is such that it comprises a freely flowable liquid, and in sprayed form, a fine mist that finds its way to and deposits on the desired mucosa.

Id, (*Id* at col. 4, l. 39-53), and

> For convenience, the viscosity of the composition at rest is referred to as the "setting viscosity" and the viscosity of a composition which is shaken is referred to as the "shear viscosity". As mentioned above, the setting viscosity of the composition should be sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition and to retain for an extended period of time the composition on the mucosal surfaces on which it is deposited in the nasal cavities, that is, the composition resists being swept away by the mucocillary forces which are present in the nasal cavities. The shear viscosity of the composition is sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist.

Id, (*Id* at col. 4, l. 63, col. 5, l. 9). The detailed description of the invention also provides a test that one can use to determine if a composition falls within the scope of the claims:

> Suitable values for the setting viscosity and for the shear viscosity of the composition can be determined for a particular composition, taking into account also the particular means used to apply the composition to the nasal cavities. By way of example, a setting viscosity of about 400 to about 800 cp is recommended for a composition containing an anti-inflammatory steroid, for example, triamcinolone acetonide. A recommended shear viscosity for such a composition is about 50 to about 200 cp. Viscosity is measured using a Brookfield Synchro-Letric viscometer (Model LVT). The viscosity is measured at 20° C. The setting viscosity is measured after mixing at 30 rpm for 30 seconds. The shear viscosity is measured by mixing at 30 rpm for 30 seconds after mixing on a Burrell wrist-action shaker at full speed for 5 minutes.

Id, (*Id* at col. 5, l. 10-24).

C. Prosecution of the '573 Patent

The '465 application underlying the '573 patent was filed on July 3, 1996. A1. As originally filed, the '465 application had 20 claims directed to methods for applying solid particles of a medicament to the mucosal surfaces of the nasal cavities, aqueous pharmaceutical compositions which are capable of being sprayed in the nasal cavity of an individual, and methods for preparing an aqueous pharmaceutical composition.

In the first Office Action, the Examiner rejected all of the claims under § 102 or § 103. A81 - A86 ('573 File History, paper 2). The anticipation rejections were based on Settipane *et al.* (1995), Kobayashi *et al.* (1995), or Suzuki *et al.* (U.S. Patent No. 4,294,829); the obviousness rejections were over Suzuki *et al.* in view of Weg (U.S. Patent No. 5,543,434) and June (U.S. Patent No. 5,429,824). *Id.* The inventor responded to the Settipane *et al.* and Kobayashi *et al.* rejections by pointing out that those articles, which discussed clinical trials, do not disclose the formulation of the drugs involved. A100–A105 ('573 File History, paper 3). With regard to the Suzuki *et al.* patent, he noted that the reference "discloses a powdery pharmaceutical composition," and not "an aqueous composition of the medicament." A101-A104 ('573 File History, paper 4, at 11-14). The inventor further argued against the obviousness rejection by pointing out that the Weg patent "discloses an aqueous nasal spray composition for the treatment

of pain . . . [that] does not disclose that the composition has thixotropic properties," and that the June patent does not disclose thixotropic properties at all. A105-A106. Moreover, one skilled in the art would not be induced to combine these references because they relate to fundamentally different types of compositions. *Id*. Contemporaneously, the inventor also filed an Information Disclosure Statement in which he both disclosed potentially relevant references and discussed his invention. A117-A129 ('573 File History, paper 6).

The Examiner maintained the rejections, causing the inventor to file a Continued Prosecution Application, in which he cancelled the pending claims and submitted 19 new claims. '573 File History, paper 11. A Second Preliminary Amendment added 16 additional claims. '573 File History, paper 13. The inventor also submitted the Declaration of Brandon Simpson, which set forth the factual reasons why Kobayashi *et al.* and Settipane *et al.* are not invalidating prior art, then held a teleconference with the Examiner on February 22, 1999. A208-A211 ('573 File History, paper 17.) The Examiner then allowed the claims on March 3, 1999. A205-A207 ('573 File History, paper 16). The Examiner subsequently issued a Notice of Allowability on March 17, 1999, explaining that the "claimed composition [comprises] unique thixotropic properties, with specific viscosity traits," and that the claimed invention was not taught or suggested in the prior art. A215 ('573 File History, paper 19, page 2) ("Moreover, the applicant's records showed the unexpected results of efficacy in the studies conducted with regard to the effective dose and other beneficial traits . . . .").

D. The '329 Patent

The '329 patent, also entitled "Aqueous-based Pharmaceutical Composition," issued on November 7, 2000 from a continuation of the '573 patent. A12. Specifically, the '329 patent issued from Application Serial No. 09/315,454 ("the '454 application"), which claimed a right of

priority to the July 3, 1996 filing date of the '465 application. *Id.* Aventis is asserting independent claims 1, 6, 13, 14, and 25 of the '329 patent against Barr, as well as dependent claims; again, all of the claim construction disputes arise out of the language of the independent claims. The asserted independent claims of the '329 patent recite as follows (with disputed terms bolded):

> 1. An **aqueous pharmaceutical composition** which is capable of being sprayed into the nasal cavity of an individual, which is propellant-free, and has a pH of about 4.5 to about 7.5, and which comprises:
>
> (A) at least about 85 wt. % of water;
>
> (B) about 0.001 to about 2 wt. % of solid particles of triamcinolone acetonide;
>
> (C) about 1 to about 5 wt. % of a suspending agent comprising a mixture of about 85 to 95 wt. % of microcrystalline cellulose and about 5 to about 15 wt. % of carboxymethyl cellulose based on the weight of the mixture, the amount of suspending agent being effective to maintain said solid particles dispersed uniformly in the composition and to impart to the composition the following **thixotropic** properties:
>
> (i) **the viscosity of the composition in unsheared form is about 400 to about 800 centipoise**;
>
> (ii) **as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition is about 50 to about 200 centipoise and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity**; and
>
> (iii) **in deposited form on the mucosal surfaces, the viscosity of the composition is about 400 to about 800 centipoise and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity**; and
>
> a compound that has anti-microbial properties.
>
> 6. An article of manufacture comprising
>
> (A) an **aqueous pharmaceutical composition** which comprises: a **pharmaceutically effective amount** of solid particles of triamcinolone acetonide which is effective in treating an abnormal bodily condition by virtue of its being present on the **mucosal surfaces** of the nasal cavity and a suspending agent in an amount effective to

maintain said particles dispersed uniformly in the composition and to impart to the composition the following **thixotropic** properties:

(i) **the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein**;

(ii) **as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity**; and

(iii) **in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity**;

(B) a vessel which contains said composition; and

(C) a precompression pump which is associated with the vessel and which is capable of spraying a full dose of the composition into the nostril of an individual.

13. An article of manufacture comprising:

(A) a **thixotropic aqueous pharmaceutical composition** which is capable of being sprayed into the nasal cavity of an individual, which is propellant-free and has a pH of about 4.5 to 7.5, and which comprises (a) triamcinolone acetonide; (b) a mixture of microcrystalline cellulose and carboxymethylcellulose sodium; (c) Polysorbate 80; (d) disodium ethylenediamine tetraacetate; (e) benzalkonium chloride; (f) dextrose; and (g) purified water;

(B) a vessel which contains said composition; and

(C) a precompression pump associated with the vessel and which is capable of spraying a full dose of the composition into the nostril of an individual.

14. A method for treating allergic rhinitis in an individual comprising the administration to said individual of an **aqueous thixotropic pharmaceutical composition** comprising:

(A) a **pharmaceutically effective amount** of solid particles of triamcinolone acetonide which is effective in treating allergic rhinitis by virtue of its being present on the **mucosal surfaces** of the nasal cavity of the individual; and

(B) a suspending agent in an amount effective to maintain said particles dispersed uniformly in the composition and to impart to the composition **thixotropic** properties; by spraying a full dose of the composition in the form of a readily flowable atomized mist

> into one of the nostrils of the individual for deposit on the **mucosal surfaces** of the nasal cavity in the form of a viscous composition which resists being cleared from the **mucosal surface**s by the inherent mucocillary forces which are present in the nasal cavity.
>
> 25. A method for delivering an **aqueous thixotropic pharmaceutical composition** comprising triamcinolone acetonide to each of the **mucosal surfaces** of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the **mucosal surfaces** which overlie the turbinates covering the conchas comprising spraying a full dose of the composition in the form of a readily flowable atomized mist into each nostril of the individual and allowing said sprayed composition to deposit on said surfaces in the form of a viscous composition which resists being cleared from the **mucosal surfaces** by the inherent mucocillary forces which are present in the nasal cavity.

The specification is the same as the specification of the '573 patent, with the exception of a claim of priority.

E. The Prosecution of the '329 Patent

The '454 application was filed on May 20, 1999, and therefore was co-pending with the '465 application from which it is a continuation. A12. The application was filed with the same 29 claims that eventually issued in the '329 patent. In an August 12, 1999 Office Action, the Examiner rejected all of the claims due to non-statutory double-patenting, but otherwise found the claims allowable. A303 ('329 File History, paper 5, page 4). In response, the inventor filed a terminal disclaimer, causing the Examiner to withdraw the rejection and allow the '329 patent to issue. A307 ('329 File History, paper 6, page 2); A309-310('329 File History, paper 7, pages 1-2) (Terminal Disclaimer to Overcome A Double Patenting Rejection (37 CFR §1.321(c) dated November 12, 1999)); A311-A315 ('329 File History, paper 8).

IV. ARGUMENT

A. Legal Standards for Claim Construction

As this Court knows, the meaning of the claims is determined by interpreting the claim language through the eyes of one of ordinary skill in the art, in light of the intrinsic evidence – the

patent specification, the prosecution history, and the other claims – as well as any relevant extrinsic evidence. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). However, because extrinsic evidence is generally "less reliable than the patent and its prosecution history in determining how to read claim terms," when the intrinsic evidence is clear, claim interpretation should be based solely upon that intrinsic evidence without resort to extrinsic evidence. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (en banc); *see also Vitronics*, 90 F.3d at 1583; *Markman*, 52 F.3d at 981. Also helpful are canons of claim construction. *See, e.g., Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1328 (Fed. Cir. 2006) (the scope of a term depends on the context in which it is used, and a term that is used multiple times need not always have the same scope provided the term is modified differently each time); *Markman*, 52 F.3d at 979-981 (it is improper to import limitations from preferred embodiments into claim terms); *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995) (the same language has to mean the same thing in every claim); *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (no claim language may be interpreted as mere surplusage); *Unique Concepts, Inc. v. Brown.*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) (all the limitations of a claim must be considered meaningful). In this case, the plain meaning of the claim terms should control because the intrinsic evidence and canons of construction serve only to reinforce that plain meaning.

Interpretation of patent claims begins with an examination of the claim language itself because "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314; *see also Vitronics*, 90 F.3d at 1582. Claim language, including disputed terms, should be construed in the context of the claims as a whole. *Datamize*,

LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1348 (Fed. Cir. 2005). In that context, every word has meaning; one of the basic tenets of claim construction prohibits viewing *any* claim language as mere surplusage. *See, e.g.*, *Texas Instruments*, 988 F.2d at 1171; *Unique Concepts*, 939 F.2d at 1562 ("All the limitations of a claim must be considered meaningful . . . ."). Furthermore, when different claims use the same language, those terms must be interpreted consistently in the different claims. *Southwall*, 54 F.3d at 1579.

Although claim construction must start with the claim, the Court must consider the context of the specification as well. *Markman*, 52 F.3d at 979-80. The specification "is the single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582. That is, the written description and drawings must be consulted to determine if the patentee has specially defined the term or otherwise limited the scope of the claim. *Phillips*, 415 F.3d at 1316. However, the written description is not a substitute for the chosen claim language, nor can the written description be used to rewrite the claims. *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1364-65 (Fed. Cir. 2003). Though understanding the claim language can be aided by the explanations provided in the written description, it is improper to import into a claim limitations that are not a part of the claims. *Id.* (citing *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048 (Fed. Cir. 1994)). This rule exists "not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." *Phillips*, 415 F.3d at 1323.

The prosecution history is also relevant to the claim interpretation process because it demonstrates how the inventor and the Patent Office understood the invention, and may contain statements which limit the scope of the invention. *Vitronics*, 90 F.3d at 1582-83. The

prosecution history includes not only the representations made by the patentee and Patent Office, but also the prior art cited during the prosecution. *Kumar v. Ovonic Battery Co.*, 351 F.3d 1364, 1368 (Fed. Cir. 2003) ("prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence"). In addition, the prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application. *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349-50 (Fed. Cir. 2004).

Beyond the intrinsic evidence, extrinsic evidence such as dictionaries (including technical dictionaries) and learned treatises may be used to aid in claim construction. *Phillips*, 415 F.3d at 1317-19; *Markman*, 52 F.2d at 980-981. However, the extrinsic sources should be used as a supplement to the intrinsic evidence only "as long as those [extrinsic] sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Phillips*, 415 F.3d at 1324.

B. Proper Construction of Disputed Claim Terms

1. "Aqueous pharmaceutical composition"

Aventis contends that the term "aqueous pharmaceutical composition," as used in all of the asserted independent claims, means "a water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation." *See, e.g.*, '573 Joint Claim Construction Chart at 1. The parties agree that the term requires that the composition be water-based and include a medicament (or drug); Barr seeks to omit any requirement that the ingredients be effective and non-toxic despite agreeing that the composition "can be sprayed into the nasal cavity of a human

being." *Id.* Barr's construction not only defies common sense – it would consider a product a "pharmaceutical composition" even if the composition would kill the patient – it violates the plain meaning of the term, the language of the specification, and the prosecution history. Thus, this Court should adopt Aventis's claim construction.

In the context of the language of the claims, it is clear that the ingredients of the "aqueous pharmaceutical composition" are required not to kill the patient, not to interfere with the function of the drug, and not to cause undue irritation. First, it is undisputed that the claimed compositions are to be used by human beings. *See* '573 Joint Claim Construction Chart at 1 ("capable of being sprayed into the nasal cavity of an individual" is defined by indicating that the composition can be sprayed into the nasal cavity of a human being). It would defy logic to suggest that a composition would be an acceptable pharmaceutical if it killed the human being to whom it was administered. But if there were any question, it is answered by the claim requirement that the compositions must include an amount of TAA that "is effective in treating an abnormal bodily condition." *See* A9-10 ('573 patent, claim 1). Any treatment of an abnormal condition would be prevented by the killing of the patient. Similarly, the requirement that the TAA drug substance effectively treat an abnormal bodily condition indicates that the other ingredients cannot be incompatible with TAA. That same requirement, in combination with the knowledge that one of the conditions that must be effectively treated is allergic rhinitis – "an abnormal bodily condition that involves inflammation of the mucous membranes of the nose caused by allergens" – leads to the conclusion that the other ingredients must avoid tissue irritation. '329 Joint Claim Construction Chart at 9 (Claim 14). The TAA medicament could not treat nasal inflammation effectively if the other ingredients were irritating the same tissues.

Thus, the context of the claims dictates that the other ingredients of the "aqueous pharmaceutical composition" be pharmaceutically acceptable.

Aventis's definition is also the only one supported by the specification and prosecution history. Both Aventis and Barr cite the same sentence from the specifications as intrinsic support for their definitions: Aventis relies upon the entire sentence, Barr cuts it off without explanation. *See* A5 ('573 patent, col. 3, l. 45-50); A16 ('329 patent, col. 3, l. 54-59). Indeed, Aventis's definition for "aqueous pharmaceutical composition" is taken word-for-word from that sentence:

> The water-based composition of the present invention comprises a medicament in the form of solid particles and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation.

Id. The specifications also refer to the invention as "a pharmaceutical composition which has a combination of properties that make it particularly effective and suitable for relieving abnormal bodily conditions . . . ." A4 ('573 patent, col. 1, l. 64-65); A15 ('329 patent, col 2, l. 5-6). Toxicity, causing inefficacy, or irritation would make a composition particularly *ineffective* and *unsuitable*. And during prosecution, the inventor reinforced the requirements that the composition be non-toxic, efficacious, and non-irritating. *See* A98-A100 ('573 File History, paper 4, p. 8-10) (invention is a "water-based composition . . . capable of being sprayed into the nasal cavities where it performs its pharmacological function" and should "prevent irritation of nasal mucosa"); A118-A119 ('573 File History, paper 6, p. 2-3) (invention is "an aqueous composition which is capable of being sprayed into the nasal cavity of an individual and which contains a medicament that is effective in treating an abnormal bodily condition"); A192-A193 ('573 File History, paper 14, pages 1-2); A285 ('329 File History, paper 3, page 2) (invention is "an aqueous composition of triamcinolone acetonide which is capable of being sprayed into the nasal cavity of an individual and which is retained on the surface of the mucosa which line the

nasal cavities for a time sufficient to treat allergic rhinitis.") All of the intrinsic evidence is consistent with Aventis's definition; none of it is consistent with Barr's.

Under these circumstances, in which the intrinsic evidence unequivocally points to a definition, Aventis believes it would be inappropriate to rely on extrinsic evidence to alter the definition of "aqueous pharmaceutical composition." But a review of extrinsic evidence does nothing but reinforce the accuracy of Aventis's construction. "Pharmaceutical composition" is one of the most commonly used terms in drug patents – literally tens of thousands of patents have used the term in their claims.[1] As the specifications of the patents-in-suit do in this case, many of those drug patents also use the term "pharmaceutically acceptable" to describe the ingredients of such compositions as being suitable for administration to humans at relevant concentrations without any problematic physiological response. *See, e.g.*, A374 (U. S. Patent No. 5,002,969 col. 10, l. 1-9); A377 (U.S. Patent No. 5,409,901 col. 1, l. 16-27); A394 (U.S. Patent 7,265,248 col. 10, l. 1-4), and A409 (U.S. Patent No. 7,264,969 col. 4, l. 12-36). Accordingly, the term "aqueous pharmaceutical composition" as used in the patents-in-suit requires pharmaceutically acceptable ingredients which are not toxic to humans.

2. "Mucosal surfaces"

Aventis contends that the term "mucosal surfaces" means "bodily tissues which line the nasal cavity," where the nasal cavity includes, by the parties' agreement, "among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses; and the turbinates which overlie the conchas of the nasal cavities." *See, e.g.*, '573 Joint Claim

[1] According to a search run of the PTO website, over 40,000 patents use the term in the claims. http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&TERM1=Pharmaceutical+composition&FIELD1=ACLM&co1=AND&TERM2=&FIELD2=&d=PTXT

Construction Chart at 2. Barr's definition is quite similar,[2] substituting mucous membranes for bodily tissues, but importantly different in one manner: it reads the language of inclusion out and renders the claim less definite. Under these circumstances, this Court should adopt Aventis's construction.

Aventis's proposed construction is straightforward and relies only on the intrinsic evidence, namely the description of the "mucosal surfaces" in the specification. By contrast, Barr's proposed construction is tautological, relying on the undefined term "mucous membrane" to describe mucosal surfaces. Barr offers no definition for "mucous membranes," and without such a definition, it is unclear what the mucosal surfaces comprise. Aventis's proposed language makes clear that the "mucosal surfaces" are "bodily tissues which line the nasal cavity." Accordingly, this Court should adopt Aventis's proposed construction.

3. "Pharmaceutically effective amount"

Aventis contends that the term "pharmaceutically effective amount" means an amount "that exerts the pharmacological action of the medicament." *See, e.g.*, Joint Claim Construction Chart at 2. Barr agrees with that requirement, but pours additional requirements (which vary from claim to claim) into the term. The rules of claim construction and intrinsic evidence demand that the additional requirements of Barr's construction be rejected. Thus, this Court should adopt Aventis's claim construction.

[2] The contested nature of the definition of "mucosal surfaces" is the unfortunate result of Barr's definition changing after the close of business of the day on which the Joint Claim Construction Chart was due. Had the change come earlier, the parties might have been able to reach agreement. In fact, if Barr stipulates that the term does not give rise to any written description or indefiniteness defense under 35 U.S.C. § 112, Aventis would be willing to accept Barr's construction.

Just reading Barr's proposed construction of "pharmaceutically effective amount" in the context of the claims makes it clear that Barr is improperly attempting to add requirements to the meaning of that term. Most clearly, Barr improperly proposes that the term "pharmaceutically effective amount" have different definitions in different claims. In claim 1 of the '573 patent and claim 6 of the '329 patent, Barr proposes that it mean "an amount [of triamcinolone acetonide] that exerts pharmacological action and provides relief of nasal symptoms ***caused by the abnormal bodily condition***." '573 Joint Claim Construction Chart at 1, 11; '329 Joint Claim Construction Chart at 3-6 (emphasis added). In claim 21 of the '573 patent, it proposes that it mean "an amount [of triamcinolone acetonide] that exerts pharmacological action and provides relief of nasal symptoms ***of allergic rhinitis***," and in claim 14 of the '329 patent, it proposes that it mean "an amount [of triamcinolone acetonide] that exerts pharmacological action and provides relief of nasal symptoms ***caused by allergic rhinitis***." '573 Joint Claim Construction Chart at 8; '329 Joint Claim Construction Chart at 9 (emphasis added). As a matter of law, unless there is some modifying language to suggest otherwise, the same language has to mean the same thing in every claim. *Southwall*, 54 F.3d at 1579; *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1328 (Fed. Cir. 2006). Here, there is no modifying language to save Barr's proposed construction – to the contrary, as discussed below, the surrounding language of the claims makes it clear that Barr's proposed construction is wrong. Thus, the Court should reject Barr's proposed construction and accept Aventis's.

Viewing the term "pharmaceutically effective amount" in context, it becomes clear that Barr is seeking to pour the requirements of other portions of the claims into its proposed construction and rob those other parts of the claims of any meaning whatsoever. That is strictly prohibited in claim construction because every claim limitation must be given meaning. *See,*

e.g., *Texas Instruments*, 988 F.2d at 1171 (no claim language may be interpreted as mere surplusage); *Unique Concepts, Inc. v. Brown.*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) ("All the limitations of a claim must be considered meaningful . . . ."). For example, substituting Barr's construction into the phrase "a pharmaceutically effective amount of solid particles of triamcinolone acetonide which is effective in treating an abnormal bodily condition" of claim 1 of the '573 patent and claim 1 of the '329 patent would render the rest of the phrase meaningless. Under Barr's proposed construction, the phrase could be rewritten:

> An amount [of triamcinolone acetonide] that exerts pharmacological action and ***provides relief of nasal symptoms caused by the abnormal bodily condition*** which ***is effective in treating an abnormal bodily condition***

See, e.g., '573 Joint Claim Construction Chart at 1. In the context of those claims, however, the effect of treating the abnormal bodily condition can include providing relief of nasal symptoms. A9-A10 ('573 patent, claim 1), A21 ('329 patent, claim 1) ("An aqueous pharmaceutical composition which is capable of being sprayed into the nasal cavity of an individual . . . ."). In clear contrast to the confusion caused by Barr's proposal, Aventis's construction would not only read much more naturally, it would give meaning to all of the claim terms:

> An amount of [medicament] that exerts the pharmacological action of the medicament which is effective in treating an abnormal bodily condition

That is, Aventis's construction does not render portions of the claim mere surplusage, and therefore is the only one the Court could properly adopt.

The specifications of the patents-in-suit confirm Aventis's construction of the term "pharmaceutically effective amount." As with "aqueous pharmaceutical composition," both Aventis and Barr rely upon the same sentence for most of their construction. *See* '573 Joint Claim Construction Chart, p. 2 (citing '573 patent, col. 3, l. 59-62). Here, however, Barr attempts to graft on additional language from a preferred embodiment to form its definition of

"pharmaceutically effective amount." *Id.* (Barr citing '573 patent, col. 3, l. 65-67). It is improper to import limitations from preferred embodiments into claim terms, if the specification and claims do not clearly indicate that the limitations are part of the claim language. *Markman,* 52 F.3d at 979-981; *see also E.I, Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988), *Comark Comm'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). Here, the specifications of the patents-in-suit do disclose that relief from symptoms of rhinitis is one intended goal for the claimed compositions of the invention. A4 ('573 patent, col. 1, l. 11-16); A15 ('329 patent, col. 1; l. 20-25). However, they make equally clear that although "the present invention is described initially in connection with the treatment of particular forms of rhinitis, that is, an abnormal bodily condition that involves inflammation of the mucous membrane of the nose . . . [it] should be understood that the invention has broader applicability." A4 ('573 patent, col. 1, l. 11-16); A15 ('329 patent, col. 1, l. 20-25). Thus, the intrinsic evidence makes it clear that Barr is improperly attempting to import limitations from the specifications.

As with the term "pharmaceutical composition," thousands of patents support Aventis's construction of the term "pharmaceutically effective amount," if the Court wished to review extrinsic evidence. In most of these patents – over 3,000 use the term in the claims – the phrase "pharmaceutically effective amount" is not expressly defined because the meaning is so well-established. Those patents that do expressly define these terms associate them with their well-understood and widely accepted meaning. For example, the term "pharmaceutically effective amount" has been used to refer to "an amount of a pharmaceutical compound or composition having a therapeutically relevant effect" and an "amount sufficient to ameliorate, prevent or cure [a] disorder." A427 (U.S. Patent No. 7,259,188 col. 9, l. 58-61); A434 (U.S. Patent No.

7,259,180, col. 2, l. 32-34). Thus, the extrinsic evidence would support the same definition as provided in the intrinsic evidence, and Aventis's construction is correct.

4. "Thixotropic"

Aventis contends that the term "thixotropic," as used in all of the asserted claims, "refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed." *See, e.g.,* '573 Joint Claim Construction Chart at 2. Thixotropy is a rheological effect well-known to those of skill in the art (even if how to cause it is not), and recognized – if not known by name – by the general public.[3] Aventis therefore suggests adoption of the ordinary meaning of the term, which is supported by the intrinsic evidence. But instead of applying the ordinary meaning of "thixotropic," Barr takes the remarkable position that "thixotropic" has no meaning in some claims and an extremely detailed meaning unique to this invention in other claims. The effect of Barr's proposed construction would be to make all of the claims mean the same thing, violating the doctrine of claim differentiation. Thus, only Aventis's proposed construction of "thixotropic" comports with the law of claim construction.

"Thixotropic" is a term of art and, therefore, consulting extrinsic evidence, such as dictionaries and learned treatises, would be proper in interpreting how one skilled in the art would understand the term. *Phillips*, 415 F.3d at 1318 ("Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of

[3] Ketchup is an example of a thixotropic composition. At rest, it is a thick product that resists being poured out of the bottle. As the bottle is pounded, shaken, or stirred, it thins and becomes far easier to pour. After being poured for the first time, the ketchup is far easier to pour until the structure recovers and the product becomes thick again.

skill in the art of the invention.") A seminal treatise in rheology is "An Introduction to Rheology," by H.A. Barnes, J.F. Hutton, and K. Walters ("Barnes"). A450. Barnes defines thixotropy as:

> A decrease of the apparent viscosity under constant shear stress or shear rate, followed by a gradual recovery when the stress or shear rate is removed. The effect is time-dependent.

A454; '573 Joint Claim Construction Chart at 2, '329 Joint Claim Construction Chart at 1.[4] Aventis's construction of "thixotropic" is based on the Barnes definition of thixotropy.

The claims make it clear that Aventis's construction of "thixotropic" is accurate. Certain claims (claim 34 of the '573 patent; claims 13, 14, and 25 of the '329 patent) use the term in isolation, but other claims (claims 1 and 5 of the '573 patent; claims 1 and 6 of the '329 patent) identify "following thixotropic properties." A11 ('573 patent claim 34); A21-A22 ('329 patent claims 1 and 6); A9-A10 ('5783 patent claims 1 and 5); A21 ('329 patent claims 1 and 6). Those claims that identify "following thixotropic properties" describe rheological properties that vary from claim to claim. For example, claim 1 of the '573 patent and claim 6 of the '329 patent describe a thixotropic composition in which the viscosity in unsheared form is "relatively high," the viscosity of the composition when subjected to shear becomes "relatively low," and the viscosity of the composition after deposition on mucosal surfaces again becomes "relatively high." A9 ('573 patent claim 1); A21 ('329 patent claim 6). Claim 5 of the '573 patent and claim 1 of the '329 patent provide specific viscosity range limits, describing the viscosity at rest

[4] Other treatises confirm Barnes' definition. *See, e.g.*, U.S. Patent No. 5,300,302 col. 4, l. 54-59; U.S. Patent No. 3,035,984 col. 3, l. 4-6; Determining and Measuring Thixotropy and Rheology for Coating Applications Using Equipment from Malvern Instruments, *available at* http://www.azom.com/details.asp?ArticleID=2883 (last visited Sept. 10, 2007) (citing Bohlin application note MRK584-01 "Determining and measuring thixotropy"); Clyde M. Ofner & Roger I. Schnaare, FMC BIOPOLYMER, *Suspensions*, § 9, 17, (FMC Corporation, 2000).

as being "about 400 to about 800 [centipoise]," the sheared viscosity as being "about 50 to about 200 [centipoise]," and the deposited form restructuring to "about 400 to about 800 [centipoise]." A10 ('573 patent claim 5); A21 ('329 patent claim 1). Notably, dependent claim 35 of the '573 patent sets forth different specific limits on the range of viscosity in unsheared form ("about 400 to about 1000 centipoises"), the same numerical limits on sheared viscosity, and *no specific limits on deposited viscosity*. A11. Because all of these varying rheological properties are described as "thixotropic," the context of the claims makes it clear that "thixotropic" does not indicate any specific viscosity limits. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1348 (Fed. Cir. 2005). Aventis's construction is therefore consistent with the claims.

In contrast to the consistency between Aventis's construction of "thixotropic" and the claims, Barr's proposed construction seeks to impose a definition that either results in the term having no meaning whatsoever, or having different meanings in different claims. In claims 1 and 5 of the '573 patent and claims 1 and 6 of the '329 patent, Barr defines "thixotropic" as "the specific thixotropic properties [that] are described in the claim at (i)-(iii)." A9-A10 ('573 patent claims 1 and 5); A21 ('329 patent claims 1 and 6). Such a definition renders the term meaningless, in that it could be removed from the claim and there would be no change in claim scope. That would be improper. *See, e.g., Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed. Cir. 1996) (rejecting the district court's claim construction because it rendered superfluous the claim requirement for openings adjacent to the end walls); *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (no claim language may be interpreted as mere surplusage); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) (basic tenet of claim construction requires that all limitations of a claim must be considered meaningful). To the extent that it would not be meaningless, the term "thixotropic"

in those claims would have different meanings – it would impose specific numerical viscosity limitations in claim 5 of the '573 patent and claim 1 of the '329 patent, but only "relatively high" and "relatively low" viscosity limitations in claim 1 of the '573 patent and claim 6 of the '329 patent. That too would be improper. *Southwall Techs. v Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995)

Barr's changing definitions of "thixotropic" grow clearer and more egregious in those claims that do not include a discussion of the composition's thixotropic properties. In those claims (claim 34[5] of the '573 patent and claims 13 and 25 of the '329 patent),[6] Barr provides an extended definition of "thixotropic" as:

> At rest the composition is a gel with a setting viscosity (or, viscosity at rest) that is sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition. The composition has a shear viscosity (or, viscosity when shaken) that is lower than the setting viscosity and is sufficiently low to maintain the particles suspended in the composition and to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity (or, viscosity at rest). That setting viscosity is sufficiently high to maintain the particles suspended in the composition and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucocillary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes.

[5] The language of Barr's construction of Claim 34 contains several typographical differences and one substantive difference from their construction of Claims 13 and 25 of the '329 patent.

[6] It is unclear how Barr proposes "thixotropic" should be construed in claim 14 of the '329 patent. On one hand, it states, "The specific thixotropic properties are described below." '329 Joint Claim Construction Chart at 10. The claim, however, does not have an express description of any thixotropic properties. Instead, Barr includes its lengthy alternative definition as part of its proposed construction of "by spraying a full dose of the composition in the form of a readily flowing atomized mist into one of the nostrils of the individual for deposit on the muscosal surfaces of the nasal cavity in the form of a viscous composition which resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity." '329 Joint Claim Construction Chart at 9-11.

'573 Joint Claim Construction Chart at 11-14; '329 Joint Claim Construction Chart at 7-9, 12-14. Again, it is improper to have different definitions for the same term in different claims. *Southwall*, 54 F.3d at 1579. But Barr's definition in those claims is more egregious because it breaks two canons of claim construction at once – Barr is reading the entirety of a single preferred embodiment's characteristics into the claims. *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1364-65 (Fed. Cir. 2003). For example, nothing in the term "thixotropic" requires recovery upon "immediate contact," recovery to "setting viscosity," or relates in any way to residence time in the nasal cavity. Indeed, use of the term "thixotropic" indicates that recovery is <u>not</u> "immediate." A454 (Barnes). Thus, each of Barr's proposed constructions of "thixotropic" is erroneous.

Nothing in the specification or prosecution history would suggest that the precise limitations of a preferred embodiment should be read into the meaning of the term "thixotropic." The specification repeatedly discusses "the following thixotropic properties" in much the same way that the claims do, but never indicates that those are the only properties that are "thixotropic." A98-A100 ('573 File History, paper 3, pages 8-9). Nor is there any express definition of the term "thixotropic." Similarly, the term "thixotropic" was used in the prosecution of the patents-in-suit in much the same manner, but was never specifically defined. *See, e.g.*, A191 ('573 File History, paper 10, page 9). In short, nothing in the other intrinsic evidence varies what the ordinary meaning and context of the claims establish as the definition of "thixotropic." This Court should therefore adopt Aventis's definition.

5. "The viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein"

Aventis contends that the term "the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein" means "the viscosity of the composition at rest during non-use is sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition." *See, e.g.*, '573 Joint Claim Construction Chart at 2. As defined in the specifications of the patents-in-suit, "relatively high viscosities range from about 400 to about 1000 cps when measured by the method disclosed in the specification." *Id.* Barr proposes a construction that ignores the specifications' definition of "relatively high" and improperly separates the requirement of "being a gel having said particles suspended therein." In the context of the patents-in-suit, only Aventis's construction can be correct.

The specification not only identifies a definition for "relatively high," it also identifies how to determine whether viscosity is "relatively high." The definition for relatively high, cited as support by both Aventis and Barr in the Joint Claim Construction Statement, states, "The viscosity of the composition at rest is relatively high, for example, about 400 to about 1000 cp." A5 ('573 patent col. 4, l. 39-41); A16 ('329 patent col. 4, l. 48-50). That is, the specification provides a scale, in comparison to which the viscosity is "relatively high." Barr suggests that "relatively high" should be measured against sheared viscosity, but nothing in the claims, specification, or prosecution history supports such an assertion. Furthermore, Barr ignores that the specification indicates the methodology for determining whether viscosity is "relatively high" – the specification provides:

> Viscosity is measured using a Brookfield Synchro-Letric viscometer (Model LVT). The viscosity is measured at 20º C. The setting viscosity is measured after mixing at 30 rpm for 30 seconds. The shear viscosity is measured by mixing at 30 rpm for 30 seconds after mixing on a Burrell wrist-action shaker at full speed for 5 minutes.

A6 ('573 patent col. 5, l. 18-24); A17 ('329 patent col. 5, l. 27-33). Because measured viscosity may depend on the method (and equipment) for measurement, it would be improper to leave out the requirement that the "relatively high" viscosity be determined according to the methodology set forth in the specification.

Although both parties cite the same sentence regarding the nature of the composition as a "gel having [TAA] particles suspended therein," Barr chooses to separate the phrase into two requirements. That sentence states:

> The thixotropic nature of the composition at rest (not subject to shear) can be described as a gel in which the particles of medicament are dispersed and suspended substantially uniformly.

A5 ('573 patent col. 4, l. 36-39); A16 ('329 patent col. 4, l. 45-48). That is, the specification indicates that the composition at rest is not any type of "gel," but instead a "gel in which the particles of medicament are dispersed and suspended substantially uniformly." Separating the requirement into being a "gel" and "having [TAA] particles suspended therein" would be clearly erroneous because a basic definition of a "gel" is a colloidal system (that is, a type of suspension) with certain properties of a solid; the claims and specification indicate the properties – substantially uniform dispersal and suspension of particles – on which to focus. By dividing the term in two, Barr attempts to undo the intent expressed in the claims and specification to have the substantially uniform dispersal and suspension of particles be the hallmark of the "gel having [TAA] particles suspended therein." The error in dividing the limitation is compounded by Barr's failure to construe the "gel" portion at all; it is unclear how, if at all, Barr believes that word should limit the scope of the claims. Similarly, it is unclear if Barr intends to introduce some other test – which is not supported by the claims, specification, or prosecution history – to

determine if a product is a "gel" within the scope of the claims. As a result, only Aventis's construction is supported by the intrinsic evidence.

Moreover, as discussed above, Barr's construction for this claim term highlights again why Barr's proposed extended definition for "thixotropic" is inappropriate. *See supra*, p. 25. Barr's proposed extended construction includes a statement that "[a]t rest the composition is a gel with a setting viscosity (or, viscosity at rest) that is sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition." *See, e.g.*, '573 Joint Claim Construction Chart at 2. That is, if the Court were to accept Barr's extended definition for thixotropic, the entirety of this term would be mere surplusage. That would be unacceptable under the law of claim construction. *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991).

6. "As the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity"

Aventis contends that the term "as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity" means "upon application of shear force such as shaking, the viscosity of the composition decreases sufficiently to allow the composition to flow freely through a pump orifice and break up into a fine mist that can infiltrate and deposit on mucosal regions." *See, e.g.*, '573 Joint Claim Construction Chart at 3. As used in the claims, "relatively low viscosities range from about 50 to about 200 cps when measured by the method disclosed in

the specification." *See, e.g., id.* Barr's definition fails to define "relatively low" at all, contravening the structure of the claims and the specification. Thus, the Court should adopt Aventis's construction.

The structure of the claims, confirmed by the specification, dictates that the viscosity of the sheared composition be both "relatively low" and such that it flows readily in the form of a mist. *See, e.g., id.* The claims could have been written to require that the viscosity be "relatively low such that the composition in the form of a mist flows readily" as a single requirement; they were not written that way. And if there were any uncertainty, it is answered in the specification. The specification both separates the two requirements in wholly separate clauses and defines "relatively low:"

> As the composition is subjected to shear forces, for example, upon being subjected to forces involved in its being agitated before spraying, the viscosity of the composition decreases (for example, to about 50 to about 200 cp) and it flows readily through the spray device and exits therefrom in the form of a fine plume . . . .

A5 ('573 patent col. 4, lines 41-51); A16 ('329 patent col. 4, l.50-60). Thus, "relatively low," like "relatively high," has a numerical viscosity measurement associated with it. Also like "relatively high," the specification indicates how to measure it. *See, e.g., id* at 2-3. Thus, only Aventis's definition comports with the intrinsic evidence.

Moreover, as discussed immediately above, Barr's construction for this claim term highlights why Barr's proposed extended construction of "thixotropic" is inappropriate. Barr's extended proposed construction for "thixotropic" includes the following sentence, which covers much of the same ground as its proposed construction of "as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively

low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity:"

> The composition has a shear viscosity (or, viscosity when shaken) that is lower than the setting viscosity and is sufficiently low to maintain the particles suspended in the composition and to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity.

'329 Joint Claim Construction Chart at 7-11 (providing Barr's proposed construction of "thixotropic"). Because both limitations must be given meaning in construction, Barr's proposed constructions must both fail.

7. "In deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity "

Aventis contends that the term "in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity" means "upon cessation of shear force and in relatively unstressed form following deposition on mucosal surfaces, the viscosity of the composition increases to a relatively high value such that the composition is retained on the mucosal surfaces on which it is deposited and resists being swept away by mucocillary forces, and reverts to the viscosity in unsheared form." '573 Joint Claim Construction Chart at 3; '329 Joint Claim Construction Chart at 5. In this context, "mucocillary forces are those that cause mucocillary clearance." *Id.* Aventis's construction follows closely the structure of the claims and applies only definitions found in the specification. In contrast, Barr attempts to add limitations that are found in neither the claims, specification, nor prosecution history. Specifically, nothing in the intrinsic evidence requires restructuring "upon

immediate contact with the mucosal surfaces," "return to a gel," "return to . . . setting viscosity" or retention that "must be greater than 30 minutes." Barr also attempts to read a preferred embodiment into the claim language by requiring retention "for an extended period of time." Finally, Barr fails to define "mucocillary forces" in any manner. Thus, Aventis's straightforward construction should be adopted.

Barr attempts to take remarkable liberties in construing this claim term, using language that does not appear anywhere in the patent. Barr suggests that "[u]pon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity," but *the word "immediate" does not appear in the patents-in-suit* and the terms "gel" and "setting viscosity" are used only in relation to the unsheared form, not the deposited form.[7] A5 ('573 patent col. 4, l. 36-39, 63, 65); A16-A17 ('329 patent col. 4, l. 45-48; col. 5, l. 5-8). Similarly, nothing in the specification or claims identifies 30 minutes as a time required to be retained on the mucosal surfaces. While the specification indicates that mucocillary clearance removes particles "within 10-30 minutes from the time the particles enter the nose," it does not indicate whether TAA particles are on the low end or the high end of that time continuum (or somewhere in between). A4 ('573 patent col. 1, l. 56-57); A15 ('329 patent col. 1, 64-65). Thus it would be improper to assume retention time would have to exceed any particle's residence. Because none of that language appears in the intrinsic evidence, it would be improper to add it as limitations in the claims. Instead, Aventis's construction should be adopted.

Barr then attempts to leverage its erroneous description of "setting viscosity" into limiting the claims to a preferred embodiment that is retained on the mucosal surfaces "for an extended period of time." Again, "setting viscosity" is defined in the specification only as "the

[7] The specification uses a different term – gel-like – at places to describe the deposited form. A5 ('573 patent col. 4, l. 54-55); A16 ('329 patent col. 4, l. 63-64). The use of a different term would suggest that it has a different meaning.

viscosity of the composition at rest," not either at rest or in deposited form. A5 ('573 patent col. 4, l. 63-64); A17 ('329 patent col. 5, l. 5-6). It is only in a description of the characteristics of the setting viscosity that the specification mentions retention "for an extended period of time." A5 ('573 patent col. 4, l. 66 – col. 5, l. 6); A17 ('329 patent col. 5, l. 8-15). Thus, such a limitation cannot be read into the characteristics of the composition in deposited form and Barr's proposed construction should be rejected.

In addition, Barr does nothing to construe the term "mucocillary forces," while Aventis applies the definition from the specification. The specification provides:

> In order to remain in contact with the target tissues, the medicament must be capable of resisting those forces in the nasal passages that function to remove particles from the nose. Such forces, referred to as "mucocillary clearance" . . . .

A4 ('573 patent col. 1, l. 50-57); A15 ('329 patent col. 1, l. 58-64). Given that Aventis's definition is consistent with the claims and drawn from the specification, and Barr proposes no alternative, Aventis's construction should be adopted.

Moreover, as discussed in both immediately preceding sections, Barr's construction for this claim term highlights again why Barr's proposed extended definition for "thixotropic" is inappropriate. The last three sentences of Barr's proposed extended construction provide:

> Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity (or, viscosity at rest). That setting viscosity is sufficiently high to maintain the particles suspended in the composition and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucocillary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes.

A21-22 ('329 patent claims 13 and 25). Those requirements are identical to Barr's proposal for construction of the current phrase. As a result, Barr's proposed constructions for both terms must fail.

V. CONCLUSION

For the reasons discussed herein, Aventis respectfully requests that this Court enter an order construing the disputed claim terms as set forth above.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19801
302-654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
tydon@ashby-geddes.com

Attorneys for Plaintiffs
Aventis Pharmaceuticals Inc. and
Sanofi-Aventis US LLC

Of Counsel:

Paul H. Berghoff
Joshua R. Rich
Jeremy E. Noe
McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

Dated: September 10, 2007
183975.v1